

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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| Applicant's or agent's file reference 3-05WO | | Date of mailing (day/month/year) 07 JUL 2005 |
| FOR FURTHER ACTION See paragraph 2 below | | |
| International application No. PCT/US05/04275 | International filing date (day/month/year) 09 February 2005 (09.02.2005) | Priority date (day/month/year) 09 February 2004 (09.02.2004) |
| International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 17/06 and US Cl.: 606/22 | | |
| Applicant ECLECTIC GREY MATER DESIGNS, LLC | | |

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer Julian W. Woo Telephone No. 571-272-2975 |
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Form PCT/ISA/237 (cover sheet) (January 2004)

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US05/04275

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--|-----|
| Novelty (N) | Claims <u>2-13, 18, 19, 24-28, 30, 31, 34-36</u> | YES |
| | Claims <u>1, 14-17, 20-23, 29, 32, 33</u> | NO |
| Inventive step (IS) | Claims <u>2-13, 18, 19, 24-28, 30, 31, 34-36</u> | YES |
| | Claims <u>1, 14-17, 20-23, 29, 32, 33</u> | NO |
| Industrial applicability (IA) | Claims <u>1-36</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Claims 1, 14-17, 20-23, 29, 32, and 33 lack novelty under PCT Article 33(2) as being anticipated by Thomas et al. (5,549,629). Thomas et al. disclose, in figures 2 and 4 and in col. 1, line 7-33 and col. 2, lines 11-26, a suture needle assembly, a method of suturing, or a suturing kit, where the suture needle assembly or kit includes a suture needle (8), an activatable sheath (7) or hood-shaped shield, a needle holder (13), and suture material (4); where the sheath is reversibly activatable (i.e., movable) in initially armed or disarmed configurations, where the needle comprises an aperture (9) or groove, where the sheath is substantially flush along a needle outer surface in a retracted position.

Claims 2-13, 18, 19, 24-28, 30, 31, and 34-36 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a suture needle assembly, a method of suturing, a suturing kit, or a suturing needle that includes a suture needle and an activatable sheath, where the sheath is activatable by electricity or heat, where the assembly has a sheath activator that is electrically or thermally responsive, where the sheath comprises a cylindrical projection or loop, where a needle holder comprise first and second holding tips energetically connected to an energy source, and where the suture needle comprises a unifying element connected to a needle casing and capable of preventing dissociation of needle parts.

Claims 1-36 meet the criteria set out in PCT Article 33(4), and thus a suture needle assembly or kit or suture needle industrial applicability because the subject matter claimed can be made or used in industry.

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WRITTEN OPINION OF THE
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International application No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____ which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**WRITTEN OPINION OF THE
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International application No.

PCT/US05/04275 .

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-34 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1-34 are indefinite for the following reason(s): With respect to base claim 1, it is not certain how the sheath is "activatable." That is, what characterizes sheath activation?

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